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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,808	07/27/2001	Mark John Gibbs	10338-2U1 (2441651/VPA)	2166

570 7590 03/14/2005

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,808	GIBBS ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *11-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 34* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 30 December 2004 in which claims 1 and 3-5 were amended. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 2 July 2004, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below. New grounds for rejection, necessitated by amendment, are discussed below.

Claims 1-9 and 34 are under prosecution.

Claim Objections

2. Claim 8 is objected to because it does not contain the text of the previously examined Claim 8. The text is a duplicate of Claim 9. This is considered a typographical error. For purposes of examination, Claim 8 is interpreted as the originally filed claim drawn to a "high-density array".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The claims are drawn to a set of oligonucleotide probes. The claimed probes are described by their function (e.g. "a respective promiscuous probe hybridizes to a target shared between at least two of said target polynucleotides", "wherein a predefined combination of promiscuous probes hybridizes to said at least two target sequences" and "said predefined combination providing specificity of detection") and/or by the target (e.g. "wherein at least one target polynucleotide comprise at least two target sequences shared with one or more other target polynucleotides"). The claimed probe functions and target descriptions are recitations of intended use for the claimed probes. However, the recited uses do not define structure or composition of the probes.

The courts have stated that claims drawn to a product must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

Furthermore, the above recitations include broad terminology e.g. "respective", "predefined" and "specificity". The phrases "respective promiscuous probe"', "predefined combination" and "specificity of detection" are relative phrases which are interpreted broadly to encompass any probe relationship, any combination and any degree of specificity because the claims have not provided guidance for defining the claimed "respective", "predefined" and "specificity".

4. Claims 1-4, 6 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan et al (U.S. Patent No. 5,541,308, issued 30 July 1996).

Regarding Claim 1, Hogan et al disclose a set of probes for detecting at least one target polynucleotide (e.g. *Mycobacterium avium*) from a plurality of different targets (Column 12, lines 58-Column 13, line 35). The set of probes comprises a collection of different promiscuous probes (i.e. genus-specific probes 1-4, Example 8, lines 15-53) wherein the probes are capable of hybridizing to sequences shared by at least two target sequences (i.e. Mycobacterium genus) wherein a predefined combination of promiscuous probes hybridizes to at least two targets and provides specificity of detection (Tables 22-23).

Regarding Claim 2, Hogan et al disclose the set further comprising a plurality of different predefined combination of probes, each providing specificity of detection (i.e. genus-specific probes 1-4, Example 8, lines 15-53 and species-specific probes for (*M Avium, M. intracellulare, and M. tuberculosis*)(Column 13, lines 2-35 and Tables 1-23).

Regarding Claim 3, Hogan et al disclose the set comprising at lest one probe capable of hybridizing to a unique target(i.e. *M Avium, M. intracellulare, and M. tuberculosis*) (Column 13, lines 2-35 and Tables 1-23).

Regarding Claim 4, Hogan et al disclose the set comprising at least one probe "capable" of hybridizing to a pivot sequence. The genus specific probes of Hogan et al illustrated in Table 22, are "capable" of hybridizing to a pivot sequence as defined in the specification. The specification (¶ 66) defines "pivot sequence to "refer to a target sequence that occurs in two or more of the target polynucleotides but not in all of the target polynucleotides."

Furthermore, the recitation "capable of hybridizing to" is a recitation of intended use, which does not define or describe the structure or composition of the probe. The recitation is interpreted broadly to encompass possible hybridization between any nucleotides of the probe and target.

Regarding Claim 6, Hogan et al disclose the set wherein the probes are immobilized on a solid support (i.e. magnetic bead Example 8, Column 28, lines 2-14). It is noted that the probe target complex are bound to the magnetic particles. The claim does not require the probe be immobilized prior to hybridization nor does the claim define the probe as being covalently/directly attached to the solid support. Hence, the claimed "immobilized" encompasses the complex immobilization of Hogan.

Regarding Claim 34, Hogan et al disclose a set of probes for detecting at least one target polynucleotide (e.g. *Mycobacterium avium*) from a plurality of different targets (Column 12, lines 58-Column 13, line 35). The set of probes comprises a collection of different promiscuous probes (i.e. genus-specific probes 1-4, Example 8, lines 15-53) wherein the probes are capable of hybridizing to sequences shared by at least two target polynucleotides each comprising two sequences (i.e. Mycobacterium genus) wherein a predefined combination of promiscuous probes hybridizes to at least two targets and provides specificity of detection (Tables 22-23).

Response to Arguments

5. Applicant asserts the meaning of phrases used in the claims, when interpreted in light of the specification and normal usage, differs from the interpretation above. Applicant's assertions are noted, however, limitations from the specification are not read into the claims (See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993)).

Applicant acknowledges that Hogan discloses a set of probes comprising plurality of promiscuous probes (i.e. *mycobacterium* genus) (Response, page 13). However, Applicant asserts that the probe set does not distinguish a species (e.g. *mycobacterium avium*) using the probe set. Applicant further argues that Hogan et al does not disclose a target comprising two or more sequences shared with other targets and do not disclose a combination of probes that provides specificity of detection for a single *mycobacterium* gene. The arguments have been considered but are not found persuasive because claims are drawn to a probe set, but the

arguments address the intended use of the probe set. And as stated above, the courts have stated that a product must be defined by it structure, not function. Therefore, arguments concerning the functionality of the probes are not persuasive.

6. Claims 1-4, 6-9 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Gentalen et al (U.S. Patent No. 6,306,643, filed 24 August 1998).

Regarding Claim 1, Gentalen et al disclose a set of probes for detecting at least one target polynucleotide, the set comprising a collection of different promiscuous probes capable of hybridizing to a target shared between two target polynucleotides (common probe and polymorphic site) wherein a predetermine combination of probes is capable of hybridizing to at least two target sequences providing specificity of detection (Column 2, line 51-Column 3, line 31; Column 8, line 45-Column 10, line 8 and Claim 8).

Regarding Claim 2, Gentalen et al disclose the set wherein a plurality of different combinations provides specificity of detecting a different target (Column 9, line 38-Column 10, line 8).

Regarding Claim 3, Gentalen et al disclose the set comprising at least one non-promiscuous probe capable of hybridizing to a unique target i.e. polymorphism (Column 9, line 38-Column 10, line 8).

Regarding Claim 4, Gentalen et al disclose the set comprising at least one probe that is capable of hybridizing to a pivot sequence which divides the polynucleotides into groups i.e. single species target-specific control probes (Column 13, lines 21-42).

Regarding Claim 6, Gentalen et al disclose the set immobilized on a solid support (Column 17, line 23-55).

Regarding Claims 7-8, Gentalen et al disclose the set immobilized on a high-density array (Column 11, lines 11-28).

Regarding Claim 9, Gentalen et al disclose the probes linked to the support via a spacer e.g. aminotriethoxysilane (Column 17, lines 24-30) or using the methods recited at Column 11, lines 45-61).

Regarding Claim 34, Gentalen et al disclose a set of probes for detecting at least one target polynucleotide, the set comprising a collection of different promiscuous probes capable of hybridizing to a target shared between two target polynucleotides (common probe and polymorphic site) wherein a predetermined combination of probes is capable of hybridizing to at least two target polynucleotides comprise two target sequences providing specificity of detection (Column 2, line 51-Column, line 31; Column 8, line 45-Column 10, line 8 and Claim 8).

Response to Arguments

7. Applicant asserts that the instant invention is based on a strategy for decreasing the number of probes required for detecting and distinguishing between a plurality of targets. The strategy involves "using" a set of probes to detect targets wherein the set includes a collection of promiscuous probes that hybridize to a sub-sequence shared between at least two targets. Applicant further states the strategy detects targets comprising two or more target sequences whereby different targets are identified by different combinations of probes and the number of probes in the set is less than the number of targets that are the subject of detection.

Applicant asserts that the probe sets of Gentalen et al comprise more probes than targets and sites the examples wherein three probes are used to distinguish between two allele targets. Applicant asserts that because of this difference, Gentalen et al fail to teach essential elements of the claims.

The argument has been considered but is not found persuasive because the instant claims are drawn to a set of probes. Applicant's arguments are directed to methods for using

the claimed probes i.e. the intended use. As stated above, the courts have stated that a product is distinguished over the prior art by the product, not the intended use of the product. Gentalen et al disclose a plurality of promiscuous probes (Column 8, lines 66-Column 9, line 57). The claim recitations regarding the number of targets and target sequence compositions are deemed irrelevant to the claimed probe set, because the intended use does not define or describe the probe structure or composition.

NEW GROUNDS FOR REJECTION

8. Claims 1-8 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Hogan (U.S. Patent No. 6,821,770, filed 3 May 2000).

Regarding Claim 1, Hogan discloses a probe set comprising a plurality of promiscuous probes (e.g. pan-bacterial/ pan-fungal) which hybridize to a target shared by at least two targets, and at least one target comprises two sequences shared with other (pan-bacteria & Gram+) wherein the number of probes in the set is less than the number of targets (Table 5= 41 probes < Table 6= 74 identified targets) wherein a predefined combination of probe hybridization specifically identifies the targets (Example 1, Column 40-Column 42, Tables 5-6).

Regarding Claim 2, Hogan discloses the set comprising a plurality of different predefined combinations of probes providing specificity of detection (Example 1, Column 40-Column 42, Tables 5-6).

Regarding Claim 3, Hogan disclose the set further comprising at least one non-promiscuous probe i.e. species specific (Column 40, lines 24-26).

Regarding Claim 4, Hogan discloses the set further comprising at least one pivot probe that divides two or more polynucleotides into different groups (intermediate order, e.g. Gram+) (Table 3, Column 21, lines 6-64 and Example 1, Column 40, line 21).

Regarding Claim 5, Hogan discloses the set comprising at least one degenerate probe that hybridizes to a redundant sequence (high-order e.g. pan-bacterial, Column 21, lines 6-64).

Regarding Claim 6, Hogan discloses the set immobilized on a solid support (Claim 1).

Regarding Claim 7, Hogan discloses the set immobilized on a nucleic acid array (Column 10, lines 40-47).

Regarding Claim 8, Hogan disclose the set immobilized on a high-density array i.e. DNA chip (Column 10, lines 40-47).

Regarding Claim 34, Hogan discloses a probe set comprising a plurality of promiscuous probes (e.g. pan-bacterial/ pan-fungal) which hybridize to a target shared by at least two targets, and at least two targets comprises two sequences shared with other (pan-bacteria & Gram+) wherein the number of probes in the set is less than the number of targets (Table 5= 41 probes < Table 6= 74 identified targets) wherein a predefined combination of probe hybridization specifically identifies the targets (Example 1, Column 40-Column 42, Tables 5-6).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gentalen et al (U.S. Patent No. 6,306,643, filed 24 August 1998) in view of Lockhart et al (6,329,140, issued 11 December 2001).

Regarding Claim 5, Gentalen et al disclose a set of probes for detecting at least one target polynucleotide, the set comprising a collection of different promiscuous probes capable of hybridizing to a target shared between two target polynucleotides (common probe and polymorphic site) wherein a predetermine combination of probes is capable of hybridizing to at least two target sequences providing specificity of detection (Column 2, line 51-Column, line 31; Column 8, line 45-Column 10, line 8 and Claim 8). Gentalen et al further teach the method wherein the target polynucleotide encodes a gene of clinical importance (Column 10, lines 10-18) but they do not specifically teach the probe set comprises a degenerate probe. However, Lockhart et al teach a similar probe set comprising a degenerate probe wherein the degenerate probe is useful for analyzing polynucleotides encoding polypeptide sequences of interest (Column 2, lines 22-44). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe sets of Gentalen et al by including degenerate probes for the expected benefit of analyzing clinically important polynucleotides and the encoding polypeptide sequences of interest as taught by Lockhart et al (Column 2, lines 22-44).

11. Claims 5, 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan et al (U.S. Patent No. 5,541,308, issued 30 July 1996) in view of Lockhart et al (6,329,140, issued 11 December 2001).

Regarding Claim 5, Hogan et al disclose a set of probes for detecting at least one target polynucleotide (e.g. *Mycobacterium avium*) from a plurality of different targets (Column 12, lines

58-Column 13, line 35). The set of probes comprises a collection of different promiscuous probes (i.e. genus-specific probes 1-4, Example 8, lines 15-53) wherein the probes are capable of hybridizing to sequences shared by at least two target sequences (i.e. Mycobacterium genus) wherein a predefined combination of promiscuous probes hybridizes to at least two targets and provides specificity of detection (Tables 22-23) but they do not specifically teach the probe set comprises a degenerate probe. However, Lockhart et al teach a similar probe set comprising a degenerate probe wherein the degenerate probe is useful for analyzing polynucleotides encoding polypeptide sequences of interest (Column 2, lines 22-44). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the probe sets of Hogan et al by including degenerate probes for the expected benefit of analyzing clinically important polynucleotides and the encoding polypeptide sequences of interest as taught by Lockhart et al (Column 2, lines 22-44).

Regarding Claim 7-9, Hogan et al teaches the probes are immobilized (Column 28, lines 2-14) but does not teach a high-density array of probes or linkage via a spacer. However, these elements are taught by Lockhart et al who teach the preferred immobilization of probe includes attaching probes to a high density array via a spacer i.e. linker (Column 22, lines 11-35) wherein their arrays are especially useful for distinguishing between mycobacterium species (Column 12, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Hogan et al by immobilizing the probes on a high-density array via a spacer as taught by Lockhart et al based on Lockhart's expressed suggestion to do so (Column 12, lines 1-5).

Response to Arguments

12. Regarding the rejections under 35 U.S.C. 103, Applicant relies on their arguments over Gentalen et al. Those arguments have been considered and are discussed above.

13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (U.S. Patent No. 6,821,770, filed 3 May 2000) in view of Lockhart et al (6,329,140, issued 11 December 2001).

Regarding Claim 9, Hogan discloses a probe set comprising a plurality of promiscuous probes (e.g. pan-bacterial/ pan-fungal) which hybridize to a target shared by at least two targets, and at least one target comprises two sequences shared with other (pan-bacteria & Gram+) wherein the number of probes in the set is less than the number of targets (Table 5= 41 probes < Table 6= 74 identified targets) wherein a predefined combination of probe hybridization specifically identifies the targets (Example 1, Column 40-Column 42, Tables 5-6) wherein the probe set is immobilized on a high-density array i.e. DNA chip (Column 10, lines 40-47) but they are silent regarding a spacer.

However, probes linked to a solid support via a spacer were well known in the art a the time the claimed invention was made as taught by Lockhart et al who teach the preferred immobilization of probe includes attaching probes to a high density array via a spacer i.e. linker (Column 22, lines 11-35) wherein their arrays are especially useful for distinguishing between mycobacterium species (Column 12, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the solid support of Hogan by immobilizing the probes on a high-density array via a spacer as taught by Lockhart et al based on Lockhart's expressed suggestion to do so (Column 12, lines 1-5).

Double Patenting

14. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

15. Claims 1-9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of copending Application No. 10/343,170. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Comments

16. Applicant proposal to cancel Claims 1-9 of copending application 10/343,107 upon indication that the instant claims are otherwise in condition for allowance is acknowledged. The rejection is maintained.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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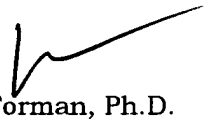

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
March 10, 2005